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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 18 October 2000
C(2000) 3025 final

NOT FOR PUBLICATION

COMMISSION DECISION

of 18 October 2000

relating to the designation of medicinal product Gemtuzumab Ozogamicin as an orphan medicinal product

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ONLY THE ENGLISH TEXT IS AUTHENTIC

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relating to the designation of medicinal product Gemtuzumab Ozogamicin as an orphan medicinal product

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products,[1] and in particular Article 5(8) thereof,

Whereas:

(1) An application concerning the medicinal product Gemtuzumab Ozogamicin was submitted by the sponsor Wyeth Europa Limited, and validated on 31 July 2000 under Article 5(4) of Regulation (EC) No 141/2000.

(2) The medicinal product Gemtuzumab Ozogamicin meets the designation criteria of Article 3(1) of the above-mentioned Regulation.

(3) The favourable opinion of the European Agency for the Evaluation of Medicinal Products, adopted by the Committee for Orphan Medicinal Products on 13 September 2000, was received by the Commission on 18 September 2000,

HAS ADOPTED THIS DECISION:

Article 1

The medicinal product Gemtuzumab Ozogamicin is hereby designated as an orphan medicinal product for the orphan indication: Treatment of Acute Myeloid Leukaemia. It shall be entered in the Community Register of Orphan Medicinal Products under the number EU/3/00/005.

[1] OJ L 18, 22.1.2000, p.1.

Article 2

The European Agency for the Evaluation of Medicinal Products shall provide to all interested parties the opinion of the Committee for Orphan Medicinal Products referred to in this Decision.

Article 3

This Decision is addressed to the sponsor: Wyeth Europa Limited, Huntercombe Lane South, Taplow, Maidenhead, Berkshire, SL6 OPH, United Kingdom.

Done at Brussels, 18 October 2000

For the Commission
Erkki Liikanen
Member of the Commission